ASSEMBLY, No. 2190

STATE OF NEW JERSEY

208th LEGISLATURE

INTRODUCED JUNE 11, 1998

Sponsored by:
Assemblyman FRANCIS J. BLEE
District 2 (Atlantic)
Assemblywoman CAROL J. MURPHY
District 26 (Essex, Morris and Passaic)

SYNOPSIS

Establishes Drug Utilization Review Board in Department of Human Services for State-funded pharmaceutical benefits programs; appropriates $90,000.

CURRENT VERSION OF TEXT

As introduced.

AN ACT establishing the Drug Utilization Review Board for State pharmaceutical benefits programs, amending and supplementing P.L.1993, c.16, and making an appropriation.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. Section 1 of P.L.1993, c.16 (C.30:4D-17.16) is amended to read as follows:

1. As used in this act:

"Beneficiary" means a person participating in a State pharmaceutical benefits program.

"Board" means the **[**Medicaid**]** Drug Utilization Review Board established pursuant to **[**this act**]** section 2 of P.L. , c. (C.)(pending before the Legislature as this bill) in connection with State pharmaceutical benefits programs.

"Compendia" means those resources widely accepted by the medical profession in the efficacious use of drugs which is based on, but not limited to, these sources: the "American Hospital Formulary Services Drug Information," the "U.S. Pharmacopeia-Drug Information," the "American Medical Association Drug Evaluations," and the peer-reviewed medical literature, and information provided from the manufacturers of drug products.

"Criteria" means those explicit and predetermined elements that are used to assess or measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes.

["Division" means the Division of Medical Assistance and Health Services in**]** "Department" means the Department of Human Services.

"Drug interactions" means the occurrence when two or more drugs taken by a recipient lead to clinically significant toxicity that is characteristic of one or any of the drugs present or that leads to the interference with the effectiveness of one or any of the drugs.

"Drug-disease contraindication" means the occurrence when the therapeutic effect of a drug is adversely altered by the presence of another disease or condition.

"Intervention" means a form of educational communication utilized by the board with a prescriber or pharmacist to inform about or to influence prescribing or dispensing practices.

"Medicaid" means the program established pursuant to P.L.1968, c.413 (C.30:4D-1 et seq.).

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

"Overutilization or underutilization" means the use or non-use of a drug in quantities such that the desired therapeutic goal is not achieved.

"PAAD" means the program of pharmaceutical assistance to the aged and disabled established pursuant to P.L.1975, c.194 (C.30:4D-20 et seq.).

"Prescriber"means a person authorized by the appropriate State professional and occupational licensing board to prescribe medication and devices.

"Prospective drug utilization review" means that part of the drug utilization review program that occurs before the drug is dispensed and is designed to screen for potential drug therapy problems based on knowledge of the patient, the patient's continued drug use and the drug use criteria and standards developed by the board.

"Retrospective drug utilization review" means that part of the drug utilization review program that assesses or measures drug use based on an historical review of drug use data against criteria and standards developed by the board on an ongoing basis with professional input.

"Standards" means the acceptable range of deviation from the criteria that reflects local medical practice and that is tested on the **[**Medicaid recipient**]** beneficiary database.

"State pharmaceutical benefits program" means the following programs: Medicaid, PAAD, the AIDS drug distribution program, and any other State and federally funded pharmaceutical benefits program.

"Therapeutic appropriateness" means drug prescribing and dispensing based on rational drug therapy that is consistent with the criteria and standards developed pursuant to **[**this act**]** P.L.1993, c.16 (C.30:4D-17.16 et seq.) and section 2 of P.L. , c. (C.)(pending before the Legislature as this bill).

"Therapeutic duplication" means the prescribing and dispensing of the same drug or of two or more drugs from the same therapeutic class when overlapping time periods of drug administration are involved and when the prescribing or dispensing is not medically indicated.

(cf: P.L.1993, c.16, s.1)

2. (New section) a. There is established the Drug Utilization Review Board in the department to advise the department on the implementation of a drug utilization review program pursuant to P.L.1993, c.16 (C.30:4D-17.16 et seq.) and this section. The board shall establish a Senior Drug Utilization Review Committee to address the specific prescribing needs of the elderly and an AIDS/HIV Drug Utilization Review Committee to address the specific prescribing needs of persons with AIDS/HIV, in addition to such other committees as it deems necessary. It shall be the responsibility of each committee to evaluate the specific prescribing needs of its beneficiary

population, and to submit recommendations to the board in regard thereto.

The board shall consist of 15 members, including the Commissioners of Human Services and Health and Senior Services or their designees, who shall serve as a nonvoting ex officio members, and 13 public members. The public members shall be appointed by the Governor with the advice and consent of the Senate. The appointments shall be made as follows: six persons licensed and actively engaged in the practice of medicine in this State, including at least two who specialize in geriatric medicine and two who specialize in AIDS/HIV care, one of whom who is a pediatric AIDS/HIV specialist, four of whom shall be appointed upon the recommendation of the Medical Society of New Jersey and two upon the recommendation of the New Jersey Osteopathic Association; one person licensed as a physician in this State who is actively engaged in academic medicine; four persons licensed in and actively practicing or teaching pharmacy in this State, who shall be appointed from a list of pharmacists recommended by the New Jersey Pharmacists Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners, Inc., the New Jersey Society of Hospital Pharmacists, the Academy of Consultant Pharmacists and the College of Pharmacy of Rutgers, the State University; one additional health care professional; and one member to be appointed upon the recommendation of the Pharmaceutical Research and Manufacturers of America.

Each member of the board shall have expertise in the clinically appropriate prescribing and dispensing of outpatient drugs.

b. All appointments to the board shall be made no later than the 60th day after the effective date of this act. The public members shall be appointed for two-year terms and shall serve until a successor is appointed and qualified, and are eligible for reappointment; except that of the public members first appointed, eight shall be appointed for a term of two years and five for a term of one year.

c. Vacancies in the membership of the board shall be filled in the same manner as the original appointments were made but for the unexpired term only. Members of the board shall serve with compensation for the time and expenses incurred in the performance of their duties as board members, as determined by the Commissioners of Human Services and Health and Senior Services, subject to the approval of the Director of the Division of Budget and Accounting in the Department of the Treasury.

d. The board shall select a chairman from among the public members, who shall serve a one-year term, and a secretary. The chairman may serve consecutive terms. The board shall adopt by-laws. The board shall meet at least quarterly and may meet at other times at

the call of the chairman. The board shall in all respects comply with the provisions of the "Open Public Meetings Act," P.L.1975, c.231 (C.10:4-6 et seq.). No motion to take any action by the board shall be valid except upon the affirmative vote of a majority of the authorized membership of the board.

e. The duties of the board shall include the development and application of the criteria and standards to be used in retrospective and prospective drug utilization review. The criteria and standards shall be based on the compendia and developed with professional input in a consensus fashion. There shall be provisions for timely reassessments and revisions as necessary and provisions for input by persons acting as patient advocates. The drug utilization review standards shall reflect the local practices of prescribers, in order to monitor:

(1) therapeutic appropriateness;

(2) overutilization or underutilization;

(3) therapeutic duplication;

(4) drug-disease contraindications;

(5) drug-drug interactions;

(6) incorrect drug dosage;

(7) duration of drug treatment; and

(8) clinical drug abuse or misuse.

The board shall recommend to the department criteria for denials of claims and establish standards for a medical exception process. The board shall also consider relevant information provided by interested parties outside of the board and, if appropriate, shall make revisions to the criteria and standards in a timely manner based upon this information.

f. The board, with the approval of the department, shall be responsible for the development, selection, application and assessment of interventions or remedial strategies for prescribers, pharmacists and beneficiaries that are educational and not punitive in nature to improve the quality of care, including:

(1) Information disseminated to prescribers and pharmacists to ensure that they are aware of the duties and powers of the board;

(2) Written, oral or electronic reminders of patient-specific or drug-specific information that are designed to ensure prescriber, pharmacist and beneficiary confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care;

(3) The development of an educational program, using data provided through drug utilization review as a part of active and ongoing educational outreach activities to improve prescribing and dispensing practices as provided in this section. These educational outreach activities shall include accurate, balanced and timely information about drugs and their effect on a patient. If the board

contracts with another entity to provide this program, that entity shall publicly disclose any financial interest or benefit that accrues to it from the products selected or used in this program;

(4) Use of face-to-face discussion between experts in drug therapy and the prescriber or pharmacist who has been designated by the board for educational intervention;

(5) Intensified reviews or monitoring of selected prescribers or pharmacists;

(6) The timely evaluation of interventions to determine whether the interventions have improved the quality of care; and

(7) The review of case profiles prior to the conducting of an intervention.

3. Section 3 of P.L.1993, c.16 (C.30:4D-17.18) is amended to read as follows:

3. The **[**board**]** department shall be responsible for:

a. **[**The adoption of regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), to carry out its responsibilities pursuant to this act.**]** Deleted by amendment, P.L. , c. (pending before the Legislature as this bill)

b. The implementation of a **[**Medicaid**]** drug utilization review program, subject to the approval of the Commissioner of Health and Senior Services, to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes, including the approval of the provisions of any contractual agreement between the **[**Medicaid**]** State pharmaceutical benefits program and other entities processing and reviewing **[**Medicaid**]** drug claims and profiles for the drug utilization review program.

The program shall include both retrospective and prospective drug utilization review. Retrospective drug utilization review shall include an analysis of drug claims processing data in order to identify patterns of fraud, abuse or gross overuse, and inappropriate or medically unnecessary care, and to assess data on drug use against standards that are based on the compendia and other sources. Prospective drug utilization review shall include a review conducted by the pharmacist at the point of sale.

c. **[**The development and application of the criteria and standards to be used in retrospective and prospective drug utilization review in such a manner as to ensure that the criteria and standards are based on the compendia and are developed with professional input in a consensus fashion with provisions for timely reassessments and revisions as necessary, and with provisions for input by persons acting as consumer advocates. The board shall also consider relevant clinical information provided by interested parties outside of the board and, if appropriate, shall make revisions to the criteria and standards based

upon this information in a timely manner. The drug utilization review standards shall reflect the local practices of physicians, in order to monitor:

(1) therapeutic appropriateness;

(2) overutilization or underutilization;

(3) therapeutic duplication;

(4) drug-disease contraindications;

(5) drug-drug interactions;

(6) incorrect drug dosage or duration of drug treatment; and

(7) clinical drug abuse or misuse.**]** Deleted by amendment, P.L. , c. (pending before the Legislature as this bill)

d. **[**The development, selection, application, and assessment of interventions or remedial strategies for physicians, pharmacists, and recipients that are educational and not punitive in nature to improve the quality of care, including:

(1) Information disseminated to physicians and pharmacists to ensure that physicians and pharmacists are aware of the duties and powers of the board;

(2) Written, oral, or electronic reminders of patient-specific or drug-specific information that are designed to ensure recipient, physician, and pharmacist confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care;

(3) The development of an educational program, administered directly by the board or through a contract with another entity, using data provided through drug utilization review as a part of active and ongoing educational outreach activities to improve prescribing and dispensing practices as provided in this act. These educational outreach activities shall include accurate, balanced and timely information about drugs and their effect on a patient. If the board contracts with another entity to provide this program, that entity shall publicly disclose any financial interest or benefit that accrues to it from the products selected or used in this program;

(4) Use of face-to-face discussion between experts in drug therapy and the prescriber or pharmacist who has been designated by the board for educational intervention;

(5) Intensified reviews or monitoring of selected prescribers or pharmacists;

(6) The timely evaluation of interventions to determine if the interventions have improved the quality of care; and

(7) The review of case profiles prior to the conducting of an intervention.**]** Deleted by amendment, P.L. , c. (pending before the Legislature as this bill)

e. The submission of an annual report, which shall be subject to public comment prior to its issuance, to the federal Department of Health and Human Services by December 1 of each year. The annual

report shall also be submitted to the Governor, the Legislature, the New Jersey Pharmaceutical Association and the Medical Society of New Jersey [Medical Society] by December 1 of each year. The report shall include the following information:

(1) An overview of the activities of the board and the drug utilization review program;

(2) Interventions used and their ability to improve the quality of care; however, this information shall not disclose the identities of individual [physicians] prescribers, pharmacists, or [recipients] beneficiaries, but shall specify whether the intervention was a result of underutilization or overutilization of drugs;

(3) The costs of administering the drug utilization review program;

(4) Any cost impact to other areas of the [Medicaid] State pharmaceutical benefits program resulting from the drug utilization review program, such as hospitalization rates or changes in long-term care;

(5) A quantitative assessment of how drug utilization review has improved [Medicaid recipients'] beneficiaries' quality of care;

(6) A review of the total number of prescriptions and medical exception requests reviewed by drug therapeutic class;

(7) An assessment of the impact of the educational program established pursuant to subsection [d. of this section] f. of section 2 of P.L. , c. (C.)(pending before the Legislature as this bill) and interventions on prescribing or dispensing practices, total program costs, quality of care and other pertinent patient patterns; and

(8) Recommendations for improvement of the drug utilization review program.

f. The development of a working agreement between the board and other boards or agencies, including, but not limited to: the Board of Pharmacy of the State of New Jersey and the State Board of Medical Examiners, in order to clarify any overlapping areas of responsibility.

g. The establishment of an appeal process for [physicians or] prescribers, pharmacists and beneficiaries pursuant to [this act] P.L.1993, c.16 (C.30:4D-17.16 et seq.) and section 2 of P.L. , c. (C.)(pending before the Legislature as this bill).

h. The publication and dissemination of medically correct and balanced educational information to [physicians] prescribers and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among [physicians] prescribers, pharmacists and [recipients] beneficiaries, including:

(1) potential or actual reactions to drugs;

(2) therapeutic appropriateness;

(3) overutilization or underutilization;

(4) appropriate use of generic drugs;
(5) therapeutic duplication;
(6) drug-disease contraindications;
(7) drug-drug interactions;
(8) incorrect drug dosage or duration of drug treatment;
(9) drug allergy interactions; and
(10) clinical abuse or misuse.

i. The development and publication, with the input of the Board of Pharmacy of the State of New Jersey, of the guidelines to be used by pharmacists, including mail order pharmacies, in their counseling of **[**Medicaid recipients**]** beneficiaries.

j. The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the **[**Medicaid**]** drug utilization review program, that identifies individual **[**physicians**]** prescribers, pharmacists, or **[**Medicaid recipients**]** beneficiaries. The board may have access to identifying information for purposes of carrying out intervention activities, but the identifying information may not be released to anyone other than a member of the board, except that the board may release cumulative nonidentifying information for purposes of legitimate research. The improper release of identifying information in violation of this act may subject that person to criminal or civil penalties.

k. The determination of whether nursing or long-term care facilities under 42 CFR 483.60 are exempt from the provisions of this act.

l. The establishment of a medical exception process by regulation.

m. The provision of such staff and other resources as the board requires.

(cf: P.L.1993, c.16, s.3)

4. (New section) The Commissioner of Human Services, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), and subject to the approval of the Commissioner of Health and Senior Services as appropriate, shall adopt rules and regulations to effectuate the purposes of P.L.1993, c.16 (C.30:4D-17.16 et seq.) and section 2 of P.L. , c. (C.)(pending before the Legislature as this bill); except that, notwithstanding any provision of P.L.1968, c.410 (C.52:14B-1 et seq.) to the contrary, the Commissioner of Human Services, subject to the approval of the Commissioner of Health and Senior Services, may adopt, immediately upon filing with the Office of Administrative Law, such regulations as the commissioner deems necessary to implement the provisions of P.L.1993, c.16 (C.30:4D-17.16 et seq.) and section 2 of P.L. , c. (C.)(pending before the Legislature as this bill), which shall be

effective for a period not to exceed six months and may thereafter be amended, adopted or re-adopted by the Commissioner of Human Services, subject to the approval of the Commissioner of Health and Senior Services, in accordance with the requirements of P.L.1968, c.410 (C.52:14B-1 et seq.).

5. There is appropriated $90,000 to the Department of Human Services from the General Fund to effectuate the purposes of this act.

6. Section 2 of P.L.1993, c.16 (C.30:4D-17.17) is repealed.

7. This act shall take effect immediately.

STATEMENT

This bill amends and supplements P.L.1993, c.16 (N.J.S.A.30:4D-17.16 et seq.), the statute which established the Medicaid Drug Utilization Review Board, to create a new 15-member Drug Utilization Review Board which, in addition to the Medicaid program, has review authority with respect to PAAD, the AIDS drug distribution program, and any other State and federally funded pharmaceutical benefits program. The members of the board shall include individuals with expertise in the prescribing of medication to the geriatric and AIDS/HIV populations. As with the current board, appointments to this new board shall be made by the Governor with the advice and consent of the Senate.

In addition, this bill provides that the board shall make recommendations to the Department of Human Services concerning the establishment of criteria for the denial of claims and a medical exception process.

Finally, the bill appropriates $90,000 to the Department of Human Services to enable it to carry out its administrative responsibilities under the bill.